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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,141 07/20/2001		Peter Emig	0691-070	9859	
23622	7590	09/27/2002			
GABRIEL			EXAMINER		
GOODWIN PROCTER L.L.P. 599 LEXINGTON AVENUE 40TH FLOOR				HABTE, KAHSAY	
NEW YORK, NY 10022				ART UNIT	PAPER NUMBER
			1624		
				DATE MAILED: 09/27/2002	g

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Defice Action Summary Examiner	•	₩.	Applicati n No.	Applicant(s)				
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Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MALING DATE OF THIS COMMUNICATION. Elementors of time may be enablated under the provisions of 17 CP1. 156(e). In an event, however, may a reply be timely filed after 50 kg (b) MONTH form the melling date of this communication. If the period for reply secribed above is test shan thirty (30) days, a reply white the statustory minerum of thirty (30) days will be considered timely. If the period for reply secribed above is test shan thirty (30) days, a reply white the statustory minerum of thirty (30) days will be considered timely. If the period for reply secribed above is test shan thirty (30) days, a reply white the statustory minerum of their (30) days will be considered timely. If the period for reply secribed by the Office later than three months after the malling date of this communication, even if timely filed, may reduce any. Status Status In the second is second and the period of the period of the communication, even if timely filed, may reduce any. Status In the second is a condition of the period of the communication, even if timely filed, may reduce any. Status In the second is a condition of the period of the communication, even if timely filed, may reduce any. Status In the second is a condition of the period of the communication of the communication. Status In the period of the period of the period of the communication of the communication. Status Application of Claims In the period of the pe		ome Action Summary	Examiner	Art Unit				
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This action is FINAL. 2b \(\times\) This action is non-final.	- Extension: after SIX (- If the peric - If NO peric - Failure to - Any reply r earned pat	EINIG DATE OF THIS COMMUNICATION is soft time may be available under the provisions of 37 CFR of MONTHS from the mailing date of this communication. In a for reply specified above is less than thirty (30) days, a right for reply is specified above, the maximum statutory perior reply within the set or extended period for reply will, by state received by the Office later than three months after the main received by the Office later than three months after the main received by the Office later than three months after the main received by the Office later than three months after the main received by the Office later than three months.	N. 1.136(a). In no event, however, may a reply be tile eply within the statutory minimum of thirty (30) day of will apply and will expire SIX (6) MONTHS from	mely filed ys will be considered timely. In the mailing date of this communication.				
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3)	i							
4a) Of the above claim(s) is/are withdrawn from consideration. 5) □ Claim(s) is/are allowed. 6) ☒ Claim(s) is/are rejected. 7) □ Claim(s) is/are rejected to. 8) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or election requirement. Application Papers 9) □ The specification is objected to by the Examiner. 10) □ The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) □ The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) □ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☒ All b) □ Some * c) □ None of: 1. ☒ Certified copies of the priority documents have been received in Application No 3. □ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) □ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) □ The translation of the foreign language provisional application has been received. 15) □ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 120 and/or 121. Attachment(s) 10 □ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 120 and/or 121. Attachment(s) □ Interview Summary (PTO-413) Paper No(s)		nce this application is in condition for allow used in accordance with the practice unde	Wance except for formal matters in	rosecution as to the merits is 453 O.G. 213.				
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3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 S. Petent and Trademark Office TO-326 (Rev. 04-01)	_			A.I				
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DETAILED ACTION

1. Claims 1-14 are now pending.

Election/Restrictions

2. Applicant's election with traverse of Group III, Claims 1-6 (in part), 7-8, and 9-14 (in part) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that (a) the number of members in a ring is not a valid ground for requiring restriction and (b) same or different "recognized class of chemical compounds" is a conclusory statement and has no bearing on the validity of restriction requirement. The examiner disagrees with applicants. Applicant's argument is in contradiction with the restriction requirement practiced in USPTO. Number of members in a ring is an important feature in defining class of compounds. For example, one skilled in the art would not consider a 6membered ring with one nitrogen such as pyridines and piperidines to be in the same category as a 6-membered ring that have two nitrogens (pyrimidines, pyrazines, pyridazines, piperazines, etc.). Thus, monoazines, diazines, and azepines do not belong to the same recognized class of chemical compounds in the art. For example, pyridines or piperidines are classified in class 546, azepines are classified in class 540, and diazines are classified in class 544. This is evidence that these are considered different classes of art.

The requirement is still deemed proper and is therefore made FINAL.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugihara et al. (US Pat. No. 4,937,246). The cited reference discloses on column 23 (WORKING EXAMPLE 11) the synthesis of 1-(2-quinolylcarbonyl)-4-(3,4,5-trimethoxybenzyl)piperazine dihydrocholride that is the same as applicants, when applicant's formula (1) has the following substituents: R,=R1-R3=H, Z=O, n=2, m=0, and R⁴ is trimethoxy substituted benzyl.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There has been recited in claim 12 a method of treating tumors in general, but the specification does not teach treatment of tumors in general.

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The claim sets forth the treatment of cancer generally. However, there never has been a compound capable of treating cancer generally. There are compounds that treat a range of caners, but no one has ever been able to figure out how to get a compound to be effective against tumors generally, or even a majority of tumors. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such a task.

Further, "tumor" covers more than just cancers. It also covers many neoplasms, cancerous or not. A neoplasm is any abnormal tissue that grows by cellular proliferation more rapidly than normal, or continues to grow after the stimulus that initiated the new growth has ceased, or shows lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such a term, also covers precancerous conditions such as lumps, lesions, and polyps. In addition, "tumor" covers things other than neoplasms. It also covers any kind of swelling arising

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from inflammation. Thus, the claim would cover treatment of many kinds of inflammation. The specification cannot support that.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, *In re Ferens*, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a. Claim 1 and claims dependent thereon are rejected because there is no definition for variables **P** and **Q**. What are they?
- b. In claim 1 (page 32, line 45), the phrase "or a a C_{2-10} heteroaryl" is incorrect. It should read as "or a C_{2-10} heteroaryl".

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Kahsay Habte, Ph. D.

Examiner Art Unit 1624

KH September 25, 2002 Mark L. Berch Primary Examiner Art Unit 1624